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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/491,624	DARDER, CARLOS PICORNELL	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-40* is/are rejected.

7)☒ Claim(s) *1, 3, 27, 31, 34, 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Request for Continued Examination filed on 10/31/05 and the Rule 132 Declarations filed on 9/1/05 is acknowledged. Claims **1-13 and 15-40** are pending in this application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/05 has been entered.

Claim Objections

Claims 1, 3, 27, 31, 34, 36 are objected to because of the following informalities: In independent claim, the examiner suggests inserting the word "water" before soluble in line 3 to read "water-soluble active". Independent claim 1, 34, and 36 contains misspellings such as alkylcarbon**il**methyl, alkoxycarbon**il**methyl or alkylsulfon**il**. The correct spelling is alkylcarbon**yl**methyl, alkoxycarbon**yl**methyl or alkylsulfon**yl**. . Claims 27 and 31 recite "aminoacids", which is a typographical error. Appropriate correction is required. Claim 3 recites "an initial size between 200 and 1800 micrometers, preferably between 600-900 micrometers". The examiner suggests claiming the narrower range in a dependent claim. Further, the examiner notes that claims 27 and 31 includes the phrase "like lysine glutamic acid..."; "bases like guanidine"; and "aminoacids like arginine...". The examiner suggests claiming the narrower range in a dependent claim(s).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 15-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 34, and 36 recite "excipient selected from the group which includes" and proper claim language is "the group consisting of". The examiner points out that the claim language "include" is synonymous to "comprising" and thus it is unclear if applicant is claiming a Markush group since "selected from the groups which includes" is not restricting claim language. Claim 34 recites "selected from the group comprising" and the proper claim language is "selected from the group consisting of".

Independent claims 1, 34, and 36 recite "substantially non-porous" which is vague and indefinite since it is unclear what the term "substantially" is intended to limit. The instant disclosure does not define "substantially" and thus it is considered indefinite since a skilled artisan would not know the metes and bounds of the claim.

Claim 1 is directed to "consisting essentially of" claim language; however the metes and bounds of this claim language is unclear. The examiner notes that applicant attempts to exclude the separating layer of the prior art (which has support in the specification). However, it is unclear if applicant is attempting to exclude other components, i.e. other active agents. If applicant is intending to exclude other active agents, then claim 35 is vague and indefinite since claim 35 recites "wherein b) comprises a single pharmaceutically active ingredient" which

implies that other active agents may be included in the dosage form and thus the claim language does not exclude other active agents. For purposes of applying prior art and for compact prosecution, the examiner will use both interpretations. However, clarification is requested since this is pertinent to Depui '184.

Claims 4 and 16 are directed to the abbreviations CMC, HPC, HPMC, which is vague and indefinite since it is unclear what the specific compound the applicant is claiming. Thus, the examiner suggests reciting the specific compound followed by the abbreviation in parenthesis. For instance, if HPC is an abbreviated form for hydroxypropylcellulose, the examiner suggests amending the claim to "hydroxypropylcellulose (HPC)".

Claims 5 and 17 are directed to "amino acids with alkaline reactions" which is indefinite since the metes and bounds of this claim are unclear. Further, the instant disclosure does not clarify what "amino acids with alkaline reactions" encompass.

Claim 8 is directed to the abbreviations CMCCa and L-HPC, which is vague and indefinite since it is unclear what the specific compound the applicant is claiming. Thus, the examiner suggests reciting the specific compound followed by the abbreviation in parenthesis.

Claims 9 and 21 are directed to the abbreviations HBC, HPMC, HMC, HPC, HPMC, PVA, which is vague and indefinite since it is unclear what the specific compound the applicant is claiming. Thus, the examiner suggests reciting the specific compound followed by the abbreviation in parenthesis.

Claims 10 and 22 are directed to the abbreviations TEC and PEG, which is vague and indefinite since it is unclear what the specific compound the applicant is claiming. Thus, the examiner suggests reciting the specific compound followed by the abbreviation in parenthesis.

Claim 32 is directed to the abbreviation HPMC, which is vague and indefinite since it is unclear what the specific compound the applicant is claiming. Thus, the examiner suggests reciting the specific compound followed by the abbreviation in parenthesis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13, 26-29, 35, and 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,132,771 to Depui et al.

Depui et al disclose an oral pharmaceutical dosage form comprising a proton pump inhibitor (abstract). More specifically, Depui et al disclose that the proton pump inhibitor can be selected from omeprazole, lansoprazole, pantoprazole, pariprazole, and leminoprazole. See column 4 to 6. Additionally, Depui discloses that the core material for their composition is a seed layered with the proton pump inhibitor along with an enteric coating. See column 8, lines 48-50.

Depui et al. also teach that the seeds can be made of different materials, including sugars. See column 8, line 58. The reference discloses mixing the proton pump inhibitor with other components prior to layering on the seeds, wherein the components can include binders, surfactants, disintegrating agents, and fillers. See column 9, lines 1-5. The binder can be selected from HPM, HPMC, CMC, PVP, sugars and starches. See column 9, lines 3-6. The alkaline substance can be selected from sodium potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, and other weak acids, as well as magnesium oxide substances, and other substances normally used in antacid compositions. See column 9, lines 27-42. The surfactant disclosed is sodium lauryl sulfate. See column 9, lines 10. Lactose monohydrate and mannitol are utilized in the examples. Depui et al disclose that the seeds have a size between 0. 1 and 2 mm, which equals 100 to 2000 micrometers. See column 8, line 62. Most importantly, Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Depui et al disclose a middle, separating layer is **optional**, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. The enteric coating layer is selected from I-IPMCP, methacrylic acid polymers, HPMC acetate succinate, and shellac. See column 10, lines 46-53. Further, the enteric coating layer includes a plasticizer: PEG or cetyl alcohol, anti-tacking agents, and pigments. See column 10, lines 58-60 and column 11, lines 1-10.

With regard to claim 35, Depui's example teach the anti-ulcer active as the only pharmaceutical in layer b. Although the examiner previously rejected that claim in combination with Lovegren, the examiner has reconsidered her position since the claims only restricts layer b.

Response to Arguments and Rule 132 Declarations

Applicant's arguments filed 10/31/05 have been fully considered but they are not persuasive.

Applicant argues that US patent 6,132,771, hereafter referred to as Depui et al, does anticipate the instant invention. Applicant argues that a single reference must show each and every feature claimed by the invention to anticipate an invention. Applicant argues that the anticipating reference must completely identify the claimed composition and must provide an enabling disclosure so that one of ordinary skill in the art can, without undue experimentation, practice the invention.

1) Applicant argues that Depui et al do not disclose or suggest a nonporous active layer.

Firstly, the examiner points out the prior art does not have to expressly state that which is inherent or implicit. The examiner points out that the applicant's claims are directed to "a *substantially* non-porous active layer or layer which disintegrates rapidly in water, made from a single aqueous or hydroalcoholic solution suspension which *comprises* the an active ingredient of anti-ulcer activity of general formula 1....and at least one pharmaceutically acceptable excipient selected from the groups which includes a binder, an alkaline reaction compound, a surface active agent, a filling material, and a disintegrating swelling excipient".

Depui discloses the seeds (inert nucleus) are layered with the proton pump inhibitor. Depui discloses the "proton pump inhibitor may be mixed with further components . Such components can be binders, surfactants fillers, disintegrating agents, alkaline additives or other and/or pharmaceutically acceptable ingredients alone or in mixtures. The binders are for example polymers such as hydroxypropyl methylcellulose (HPMC), hydroxypropylcellulose (HPC),

carboxymethylcellulose sodium, polyvinyl pyrrolidone (PVP), or sugars, starches or other pharmaceutically acceptable substances with cohesive properties. Suitable surfactants are found in the groups of pharmaceutically acceptable non-ionic or ionic surfactants such as for instance sodium lauryl sulfate." See column 8, line 53 to column 9, line 10. The examiner points further points out that example 5 discloses lanzoprazole, sugar sphere seeds, hydroxypropylmethyl cellulose, sodium laurylsulfate, and water. Instant example 2 on page 18 of the instant specification discloses lanzoprazole, sodium lauryl sulphate, hydroxypropylmethyl cellulose, crystallized disodium phosphate, lactose, hydroxypropyl cellulose, and water. The instant example and Depui's example 5 are similar and thus the layer is inherently non-porous. Again, the examiner points out that Depui need not explicitly state all inherent properties of the invention. It is noted that applicant has not pointed out specifically why Depui's active layer is non-porous, i.e. what exactly makes 771's allegedly porous.

The applicant contends Depui utilizes an alkaline substance in the active layer. The examiner points out that Depui discloses: "Further, the proton pump inhibitor *may also* be mixed with an alkaline, pharmaceutically acceptable substance (or substances). Such substances can be chosen among, but are not restricted to substances such as the sodium, potassium, calcium, magnesium and aluminium salts of phosphoric acid, carbonic acid, citric acid or other suitable weak inorganic or organic acids; aluminium hydroxide/sodium bicarbonate coprecipitate; substances normally used in antacid preparations such as aluminium, calcium and magnesium hydroxides; magnesium oxide or composite substances, such as Al2.O3.6MgO.CO2.12H 2.O, MgO.Al2.O3.2SiO2.nH2O or similar comp pH-buffering substances such as trihydroxymethyl-

aminomethane, basic amino acids and their salts or other similar, pharmaceutically acceptable pH-buffering substances." See column 9, lines 10-40.

Firstly, it should be noted that this is optional and the term optional denotes it is not a critical element. Secondly, the examiner is confused by this argument since the independent claims recite "at least one pharmaceutically acceptable excipient selected from the groups which includes a binder, **an alkaline reaction compound**, a surface active agent, a filling material, and a disintegrating swelling excipient". Claim 5 is directed to the same alkaline reaction compounds recited by Depui. Thirdly, Depui's example 5 does not include the alkaline substance. Lastly, it is unclear why applicant repeatedly argues Depui's alkaline reaction compound when applicant claims an alkaline reactions compound in all three independent claims 1, 34, and 36. Further, if applicant states that a separating layer is required if the core contains an alkaline compound, i.e. the anti-ulcer compound in its alkaline form, to provide stability, how can applicant's dosage form as claimed that may have an alkaline compound in the core and does not have a separating layer, be stable?

2) Applicant argues that all examples have a separating layer between the active layer and enteric coating. It is argued that Depui fails to enable such a dosage form. Applicant claims that Depui et al never exemplify an embodiment without a separating layer or alkaline substance. Applicant argues that Depui et al do not describe a stable and useful oral form of a proton pump inhibitor without an alkaline substance and at least one separating layer.

First, it should be noted that the applicant is wrong in the assertion that Depui does not exemplify a dosage form without an alkaline substance. As discussed above, Depui's example 5 utilizes lanzoprazole, which is not in an alkaline form. Further, the instant claims recite an

"alkaline reaction compound". Lastly, page 13 of instant specification should also be noted since it also states that the inventive dosage form can include alkaline substances, just as Depui et al state the optional use of an alkaline substance.

With regard to the separating layer, the examiner points out the separating layer is **optional**. The Webster Dictionary defines *optional* as: involving an option: not compulsory. Further, option is defined as: 1) something that may be chosen 2) an item that is offered in addition to or in place of the standard. Thus, as noted by the applicant himself, the separating layer and alkaline substance are optional embodiments. The word "optional" in itself clearly denotes that if one were to exclude the *optional* separating layer and *optional* alkaline substance, it would not be detrimental to the dosage form. With regards to applicant's argument that if the separating layer and alkaline substance are excluded, then Depui et al would not be stable and thus not enabled. Again, it is pointed out that if the separating layer and alkaline substance were absolutely critical to Depui's invention, then Depui would not insert the word optional. Additionally, column 10, lines 29-220 is pointed out wherein Depui states, "the optionally applied separating layer(s) is **not essential** for the invention."

Thirdly, the examiner points out that although Depui does not exemplify a dosage form without the optional separating layer, Depui discloses two options with the use of the word "optional", a dosage form with or without. Thus, a skilled artisan can immediately envisage the other form, i.e. the dosage form without a separating layer. Therefore, the courts have held that if one can immediately envisage an embodiment, then it is held to be anticipated. See In re Petering 133 USPQ 275 (CCPA 1962).

Lastly, with regard to the argument that Depui does not exemplify the instant invention, the examiner points out that disclosed examples and preferred embodiments do not constitute a teaching away form a broader disclosure or nonpreferred embodiment. See In re Susi. Therefore, even if for arguendo, the claims are not held to be anticipated by Depui et al, the claims are obvious since Depui et al clearly suggest the instant embodiments.

3) Applicant argues that cores that contain the alkaline substance must have a separating layer to be stable since the enteric coating contains free carboxyl groups, which can cause degradation of the omeprazole as taught by the prior art, Lovgren et al. Applicant repeatedly refers to US '505 to substantiate the argument. Applicant argues that a side-by-side comparison of Lovgren and Depui et al demonstrates that a separating layer is required.

Firstly, the examiner is unclear as to why the applicant refers to Lovgren's disclosure when addressing the arguments based solely on Depui et al since Depui does not incorporate Lovgren's disclosure by reference. As discussed previously, Lovgren's formulation is not relied upon to make the rejection of instant invention's formulation. Applicant attempts to overcome Depui by arguing the merits of Lovegren, however Depui only makes a small reference to US '505 on column 2 as a prior art proton pump inhibitor formulation but states that there are problems with the prior art formulations.

Secondly, the examiner points out that the alkaline reaction compound is *optional* and this is evidenced by **example 5 of Depui does not utilize an alkaline reaction compound in the core and Depui only uses lansoprazole which is not in an alkaline form**. Therefore, as admitted by the applicant, a separating layer is only required if an alkaline core is utilized. Thus, it is clear that one can exclude this layer from example 5 without a detrimental effect. Therefore,

clearly Depui's disclosure that the separating layer is not essential to the instant invention and optional, is applicable to example 5 and thus Depui is enabled.

With regard to Lovgren, the examiner points out that Lovgren only requires the separating layer if the core contains alkaline reacting agents.

4) Applicant argues that a mere mention of the optional embodiment does not anticipate the invention since there is undue experimentation. This scenario is analogous to a reference teaching various species. It is commonly held that if there is a laundry list of species in the prior art, the species is not clearly envisaged and thus not anticipated. However, when the species are sufficiently limited, then the species is held to be anticipated. The examiner points out that the optional embodiment disclosed by Depui renders only *two* options wherein a skilled artisan utilizes a separating layer or wherein a skilled artisan does not utilize the separating layer. Thus, one can immediately envisage the alternative and this is not undue experimentation.

5) Applicant argues that the Molina affidavit demonstrates that Depui is not enabled. Applicant argues that this declaration has been repeatedly ignored.

Firstly, the examiner points out that, for the record, both examiners have considered the declaration. However, both examiners pointed out that the declaration is not persuasive, this is not equivalent to applicant's assertion that it has not been considered. If applicant contends that the prior art is not enabling and in instant case, applicant contends Depui is not enabling, then the declaration must show that Depui is not enabled. The examiner points out that the rejection is made over Depui and not EP 0642797. Thus, applicant's arguments that EP's claims to make a stable granule and does not and the Declaration that demonstrates EP does not make a stable

granule, does not extend to Depui. Depui is a different invention with no relation to EP. It should be noted that EP teaches a different formulation than Depui.

5) Applicant argues that the Johansson's declaration demonstrates that Depui is not enabling. Applicant argues that the instant example 1 is more stable than Depui's example 5.

Firstly, the examiner notes that the Declaration states that "The results obtained in working Example 5 of US 6.132.771 where not a surprise for me, because the prior art, for instance EP0247983 (US 4,786,505) and EP244380 (US 4,853,230) cited in the patent application taught that an inert separating layer should be place between the core material and the outer enteric coating layer to avoid the contact between the anti-ulcer benzimidazole compound (omeprazole, lansoprazole, pantoprazole. etc.) and the acidic component (methacrylic copolymer) of the enteric layer. Is it also mentioned that benzimidazole compounds are not stable in acidic medium, and in contact with acidic compounds they suffer degradation and develop a strong color." Firstly, the examiner points out that US '505 and '230 state that the separating layer is required if the core contains an alkaline reaction compound.

The examiner points out that the instant invention *as claimed* is directed to the same dosage as disclosed by Depui et al. For instance, applicant argues that the instant invention does not require Depui's optional separating layer and still is stable. However, the instantly claimed invention requires the core material that comprises the anti-ulcer benzimidazole compound (omeprazole, lansoprazole, pantoprazole. etc.), the claim allows for a alkaline reaction compound, and an enteric coating polymer wherein the instant example 1 that the applicant utilizes is an acidic polymer. Thus, the same interaction must take place. Therefore, it is unclear how the instant formulation is stable versus the prior art's formulation if the only difference is

the separating layer. The applicant argues that Depui's active layer is porous but does not specify what exactly makes it porous. As noted above, it is the examiner's position that Depui's active layer has the same components as the instant claims and the instant examples and thus it is non-porous. Thus, the examiner points out that the distinguishable feature must be claimed since applicant's arguments are on the basis that the prior art is not enabled for a stable formula and the instant invention is. The feature that provides this stability must be claimed to differentiate it from the prior art. Further, applicant's arguments are contradictory and thus it is unclear as to why the instant formulation is stable versus the prior art. Applicant attributes the stability to the non-porous layer; however the instantly claimed layer is not distinguishable from Depui as discussed above. Applicant attributes this stability to the process of making the composition, but the claims do not recite this distinguishing and critical feature. Applicant asserts that the alkaline compound causes instability and thus the prior art needs a separating layer, but the applicant claims the very compound that purportedly causes the instability. This is discussed in further detail below.

Secondly, instant example 2 utilizes a specific process of making the formula. Applicant has argued that the process of making the instant invention, i.e. utilizing a Wurster fluidized bed coater, lends to the stability (Response of 10/31/05,12/3/04 and affidavit of 11/22/02). For instance, applicant clearly states "the now claimed products produced by the now claimed process have extended stability over extended periods of time". See page 18 of applicant's remarks of 10/31/05. Thus, the claims must include this distinguishable feature. The examiner does note however that Depui teaches the use of a fluid bed apparatus. Further, the examiner

notes that that applicant's example 2 comprises specific excipients in specific concentrations and it is unclear if the excipients of the instant invention contribute to the stability.

Thirdly, applicant also argues that the homogenous, non-porous layer also provides to stability. Note applicant's arguments of 10/31/05, especially page 11-12. The examiner points out that applicant's claim allow for one alkaline reaction compound. Applicant's arguments imply that the reaction alkaline compound can cause the layer to be porous. Thus, applicant cannot claim the alkaline reaction compound in all the independent claims and yet argue against its use. The applicant's arguments are contradicting the applicant's claim itself.

Lastly, the examiner notes that applicant's independent claims are drawn to several different classes of compounds and applicant emphasizes the stability of the compounds. Applicant's Rule 132 is directed t showing that a single species lanzoprazole in a specific formula is stable. However, a single species cannot apply to a genus and applicant has not shown that one can formulate a stable composition with each of the claimed classes of active compounds.

Thus, the claims must be commensurate with the scope.

Claims 1-13 and 15-40 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,365,184 to Depui et al.

Depui et al disclose an oral pharmaceutical dosage form comprising a proton pump inhibitor and an NSAID (abstract). More specifically, Depui et al disclose that the proton pump inhibitor can be selected from omeprazole, lansoprazole, pantoprazole, pariprazole, and leminoprazole. See column 4 to 6. Additionally, Depui discloses that the core material for their composition is a seed layered with the proton pump inhibitor along with an enteric coating. See

column 8, lines 48-50. Depui et al. also teach that the seeds can be made of different materials, including sugars. See column 8, line 58. The reference discloses mixing the proton pump inhibitor with other components prior to layering on the seeds, wherein the components can include binders, surfactants, disintegrating agents, and fillers. See column 9, lines 1-5. The binder can be selected from HPM, HPMC, CMC, PVP, sugars and starches. See column 9, lines 3-6. The alkaline substance can be selected from sodium potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, and other weak acids, as well as magnesium oxide substances, and other substances normally used in antacid compositions. See column 9, lines 27-42. The surfactant disclosed is sodium lauryl sulfate. See column 9, lines 10. Lactose monohydrate and mannitol are utilized in the examples. Depui et al disclose that the seeds have a size between 0. 1 and 2 mm, which equals 100 to 2000 micrometers. See column 8, line 62. Most importantly, Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Depui et al disclose a middle, separating layer is optional, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. The enteric coating layer is selected from I-IPMCP, methacrylic acid polymers, HPMC acetate succinate, and shellac. See column 10, lines 46-53. Further, the enteric coating layer includes a plasticizer: PEG or cetyl alcohol, anti-tacking agents, and pigments. See column 10, lines 58-60 and column 11, lines 1-10. The examples utilize a **Wurster-type fluidized apparatus** to coat the active agent onto the sugar core, followed by an enteric coating. See example 4.

With regard to the "consisting essentially of" language in claim 1, firstly the 112, 2nd paragraph rejection should be noted. Secondly, the examiner points out that the transitional

phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) and occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir.1998). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003). In instant case, applicant has only argued that the instant claim language excludes Depui's separating layer. Thus, it is the examiner's position that the instant claim language does not exclude Depui's NSAIDs. Further, claim 35 is directed to a single pharmaceutical in layer b which further substantiates the examiner's position that other active ingredients are not excluded in the composition.

With regard to claim 35, Depui discloses only the anti-ulcer active in layer b and the NSAID is contained in another layer. The examiner has reconsidered her position with regard to this claims since the claims only restricts layer b.

Response to Arguments

Applicant's arguments filed 10/31/05 have been fully considered but they are not persuasive.

1) Applicant argues that arguments pertaining to Depui '771 applies to Depui '184. Applicant argues that Depui '184 teaches other active ingredients.

The examiner incorporates the response to Depui '771 above.

The examiner further points out the process claims of 34 and 36 recite comprising language and thus it is not exclusionary, i.e. it does not exclude Depui's separating layer or other active ingredients. Thus, the Rule 132 declarations are not applicable to Depui '184 and cannot overcome Depui since the Rule 132 declarations are directed to providing evidence that Depui is non-enabling for a dosage form without a separating layer. Note that any showing of unexpectedness in the form of a 132 cannot overcome a 102 rejection. Therefore, applicant's arguments that Depui is non-enabling is moot with regard to claims 34 and 36 since they do not exclude the separating layer.

Secondly, with regard to claim 1's claim language and as discussed in the rejection, applicant has only argued that the instant claim language excludes Depui's separating layer. Thus, it is the examiner's position that the instant claim language does not exclude Depui's NSAIDs. Further, claim 35 is directed to a single pharmaceutical in layer b which further substantiates the examiner's position that other active ingredients are not excluded in the composition. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) and occupies a middle ground between closed claims that are written in a

consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003).

2) Applicant argues that Depui does not teach the process of making the composition.

The examiner points out that Depui's examples utilize a Wurster-type fluidized apparatus to coat the active agent onto the sugar core, followed by an enteric coating. See example 4. The applicant argues that the Depui's process requires multi-step process (such as extrusion/spheronization technique and powder layering process) and the instant invention does not require this; however it is pointed out that the process claims recite open claim language that does not exclude Depui's steps. Thus, the instant process claims are not distinguishable from the prior art.

Lastly, examiner points out that contrary to applicant's remarks, Depui '184 is different from Depui '771 in that the instant process claimed, i.e. the Wurster type fluidized bed coater in which applicant has emphasized as the critical element of the instant invention, is disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13, 26-29, 35, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,132,771 to Depui et al.

The disclosure of Depui et al has been delineated above. Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Thus, Depui et al provides two embodiments, one for a optional separating layer and the second embodiment wherein the formulation implicitly does not contain a separating layer. Depui et al disclose a middle, separating layer is ***optional***, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. Depui et al disclose the use of a fluid bed apparatus for coating. See examples. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Column 2, lines 25-31, the reference states that "combination therapy is considered for patients whose predominant symptom is

regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease."

With regard to the composition claims 1-13, 26-29, 35, and 37-38, assuming one were to argue that Depui et al do not clearly anticipate the claims since Depui et al do not explicitly state that there is no separating layer and Depui doe snot exemplify such an embodiment, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to make Depui et al's formulation with an inert core, ac active coating, and an enteric coating, excluding a the separating layer. One would have been motivated to do so since with a reasonable expectation of success since Depui clearly states that the separating layer is optional and thus the usage of the term "optional" is implicit that the formulation can functional stably without such a layer without a detrimental affect. Therefore, the removal of the separating layer is prima facie obvious to a skilled artisan.

Response to Arguments

Applicant's arguments filed 10/31/05 have been fully considered but they are not persuasive.

The examiner incorporates the above response to Depui '771 under the 102 subsection. The examiner will address applicant's arguments that have not been discussed above.

1) Applicant argues the merits of a comparison of Lovgren and Depui and the components are the same.

As pointed out above, it is unclear as to applicant's comparison of Depui with Lovegren. The examiner points out that Depui does not incorporate Lovgren's disclosure by reference. Applicant attempts to overcome Depui by arguing the merits of Lovegren, however Depui only

makes a small reference to US '505 on column 2 as a prior art proton pump inhibitor formulation but states that there are problems with the prior art formulations. Nonetheless the examiner will address the remarks. Applicant states that Lovgren's formulation and Depui's are the same. However, the examiner points out that Depui's components and Lovgren are not the same as contended by applicant. The examiner points out that Lovgren's formulation in the comparison contains an alkaline reaction compound which Depui discloses as optional. Depui discloses examples which do not contain a alkaline reaction compound. Thus, applicant's continued assertions that demonstrating Lovgren is enough to overcome Depui is incorrect since Lovgren's alkaline reaction compound may contribute to the instability and Depui does not require the alkaline reaction compound. Lovgren clearly states that the separating layer is required since the core contains omeprazole and alkaline reacting compounds.

2) Applicant argues the process of making the formulation.

The examiner points out that claim 1 does not include any process limitations and claim 1 and all those that depend on claim 1 have been discussed above.

3) Applicant's argues the merits of the process claims 34 and 36; however the examiner has withdrawn the rejection of the process claims over Depui '771 by itself. Thus, the arguments are moot.

Claims 15-25, 31-34, 36, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,132,771 to Depui et al in view of Ohno et al (4,017,647) or Wurster (2,799,241).

The teaching of Depui et al are set forth in detail above. Depui et al disclose the use of a fluid bed apparatus for coating.

Depui et al do not specify the type of fluidized bed apparatus utilized.

Ohno et al teach a method for providing an enteric coating on solid dosage forms. The enteric coating solution contains those taught in Depui et al, i.e. film-forming polymers (HPMC), plasticizers, pigments, etc. on column 2. Ohno et al teach the use of a conventional coating machine such as pan coaters, drum-type coaters, or Wurster-type fluidizing caters, and Glatt fluidizing coater since there is no principle difference between coating solid dosage forms and all conventional coaters work under the same principle of utilizing a coating solution. See column 3, lines 24-40.

Wurster teaches the Wurster-type fluidized apparatus provides for a uniformed coating an preventing the coating material from sticking to the inner surface of the chamber. See column 1, lines 22-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Depui et al and Ohno et al and utilize the fluidized apparatus of choice such as instant Wurster-type. One would have been motivated to do so since Ohno teaches that the Wurster-type apparatus among other fluid bed coaters are known and conventionally utilized in the art for coating purposes and all the coating machines work under the same principle. Therefore, it is prima facie obvious to utilize the instant Wurster-Type in Depui's process with a reasonable expectation of success since not only does Depui teach the use of a fluid bed apparatus but Ohno teaches the equivalency of all coating machines.

Further, it would have been obvious to look at Wurster and utilize the instant apparatus. One would have been motivated to do so since Wurster teaches that the Wurster-type provides a uniform coating. Further, the Wurster patent demonstrates that the Wurster-Type apparatus is not

a new type of apparatus and as been known in the art since the 1940s. Therefore, it is reasonable for a skilled artisan to utilize a conventional machine routinely utilized in the pharmaceutical coating art, this does not impart patentability.

Response to Arguments

Applicant's arguments filed 10/31/05 have been fully considered but they are not persuasive.

Applicant argues that the Wurster-type fluidized apparatus provides for a uniform coating, which eliminates the need for a separating layer and still provide a stable dosage form. Applicant argues that Ohno does not teach all coating apparatuses are equivalent and the examiner is not free to modify the disclosures.

Firstly, the examiner points out that the process claims do not exclude the separating layer and Depui's formula is thus stable. Further, applicant has not provided any evidence that the Wurster-type bed coater provide the unexpected results. For instance, the Rule 132 declaration compares the stability of Depui's formulation with or without the separating layer to show that Depui is supposedly non-enabling but the declaration does not provide any unexpected results. Further, it is unclear from this declaration and results if applicant's stability is due to the Wurster bed coater. The examiner suggests providing evidence wherein two formulas with the same components are made by different apparatuses. Secondly, the examiner points to column 3, lines 24-40 wherein Ohno clearly teaches: Any conventional coating machines, for example, pan coaters, rotary drum-type coaters, such as, Accela-Cota manufactured by Manesty Machines, England, Wurster-type fluidizing coaters developed by Wisconsin Alumuni Research Foundation, U.S.A., and fluidizing coaters such as that manufactured by Glatt, West Germany,

may be employed in the method of the invention. There is no difference in principle between the conditions with which the solid dosage forms are coated in accordance with the invention and those with which the abovementioned conventional coaters are operated using a coating solution with an organic solvent." Thus, it can be seen that the examiner has modified the teachings of the prior art.

Claims 1-13, 26-29, 35, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,365,184 to Depui et al.

The teaching of Depui et al have been delineated above. Depui teaches the use of the NSAID for its anti-inflammatory effects and the instant active for its gastric acid inhibition. Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Thus, Depui et al provides two embodiments, one for a optional separating layer and the second embodiment wherein the formulation implicitly does not contain a separating layer. Depui et al disclose a middle, separating layer is ***optional***, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Column 2, lines 25-31, the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease."

In light of the 112, 2nd paragraph rejection over the claim language and if applicant contends that the instant "consisting essentially of" language of independent claim 1 excludes

the NSAIDs of Depui '184, it is the examiner's position that that exclusion of Depui's NSAID is considered prima facie obvious.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to utilize Depui's anti-ulcer drug without the NSAID. One would have been motivated to omit an element and its function, it the element is not desired. Thus, in instant case it is obvious to exclude Depui's NSAID if one did not desire to treat pain or inflammation and only desired to treat gastric disorder.

The examiner has made this rejection for compact prosecution since the scope of the instant claim language is unclear.

Response to Arguments

Applicant's arguments filed 10/31/05 have been fully considered but they are not persuasive.

Applicant refers to the comments on '771 and argues that the rejection should be withdrawn.

The examiner has discussed Depui '771 and maintains her position.

Conclusion

All the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Sharmila S. Gollamudi
Examiner
Art Unit 1616

MICHAEL HARTLEY
PRIMARY EXAMINER